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**The Family Smoking Prevention and Tobacco Control Act: An Early
Evaluation**

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Abstract: The Family Smoking Prevention and Tobacco Control Act, enacted on June 22, 2009, gives FDA jurisdiction to regulate tobacco products “as appropriate for the protection of the public health.” This is a major change to a regulatory scheme for tobacco that has historically excluded FDA. Among other things, the Act gives FDA authority to restrict the sale and marketing of tobacco products and to require changes in the design and characteristics of tobacco products. Many aspects of the Act are controversial. This legislation has the potential to increase government control over tobacco products and their marketing, and to improve anti-smoking efforts; however, it will likely be difficult to implement in practice.

I. Introduction

On June 22, 2009, President Obama signed into law the Family Smoking Prevention and Tobacco Control Act (the “Tobacco Control Act” or “TCA”), giving the Food and Drug Administration (FDA), for the first time, explicit authority over tobacco products. The law creates a new chapter of the Federal Food, Drug and Cosmetic Act (FDCA) relating solely to tobacco and authorizes FDA to regulate tobacco products “as appropriate for the protection of the public health.”¹

The Tobacco Control Act allows FDA to act in three major areas: advertising and sales to young people, the composition of cigarettes, and representations of health effects of tobacco products. Among other things, the TCA authorizes FDA to promulgate regulations restricting the sale and marketing of tobacco products and requiring changes in the design and characteristics of current and future tobacco products, such as the reduction or elimination of harmful ingredients and additives.

Those who fought for the TCA hope it will usher in a new era of stricter tobacco regulation and a reduction in tobacco-related deaths, blaming current smoking levels on historically lax regulation. Others are doubtful. Some critics argue that the FDA is too overburdened and underfunded to regulate tobacco in addition to food, drugs, medical devices and cosmetics, and that regulating an inherently unsafe, unhealthy product is at odds with FDA’s core mission. Others believe that regulation of tobacco products is a waste of time and resources, since industry innovators will always outpace regulators, and that managing demand is the only sound way to reduce smoking levels. Some fault the Act for failing to promote less-

¹ Family Smoking Prevention and Tobacco Control Act, Preamble, Pub. L. No. 111-31 (2009).

harmful tobacco products as safer alternatives to cigarettes; while others believe it leaves open too many loopholes to have any effect.

This paper will examine the Tobacco Control Act, its history, and its goals; address some of the criticism of the Act; and evaluate its potential for success.

II. History of Tobacco Regulation

An estimated 443,000 deaths each year are attributable to tobacco use, including one-third of all cancer deaths.² Tobacco use accounts for almost \$100 billion in annual health care costs, and nearly another \$100 billion in lost productivity.³ Despite such statistics, tobacco has historically been subject to less regulation than other consumer products that enter and affect the body, such as food and drugs.

The regulatory scheme in place prior to the TCA gave several federal agencies responsibility for regulating different aspects of tobacco products at different stages of production. Under the Jenkins Act,⁴ enforced by the Bureau of Alcohol, Tobacco, Firearms and Explosives (ATFE), anyone other than a licensed distributor who ships cigarettes nationally must file monthly reports with each state tax collector listing the name and address of the person to whom the shipment was made, the brand, and the quantity thereof.⁵ The Contraband Cigarette Trafficking Act,⁶ also enforced by ATFE, makes it unlawful for any person to ship, transport, receive, possess, sell, distribute, or purchase more than a certain amount of cigarettes or smokeless tobacco, without evidence of state tax payment. The Department of Agriculture manages the Tobacco Transition Payment Program.⁷

² Centers for Disease Control and Prevention (CDC), Data and Statistics, Health Effects of Cigarette Smoking, http://www.cdc.gov/tobacco/data_statistics/fact_sheets/health_effects/effects_cig_smoking/

³ <http://www.cdc.gov/tobacco>

⁴ 15 U.S.C. § 375–378

⁵ 15 U.S.C. § 375

⁶ 18 U.S.C. § 114

⁷ See The Fair and Equitable Tobacco Reform Act of 2004, Pub. L. No. 108-357

The Federal Cigarette Labeling and Advertising Act (FCLAA)⁸ purports to “establish a comprehensive Federal Program to deal with cigarette labeling and advertising” with respect to the relationship between smoking and health.⁹ Among other things, the FCLAA requires that cigarette manufacturers annually submit to the Secretary of Health and Human Services (HHS) a list of ingredients added to tobacco in the manufacture of cigarettes, to be overseen by the CDC and the Office on Smoking and Health (OSH).¹⁰ It also mandates the now-familiar Surgeon General's health warnings on cigarettes labels and advertising and gives the Federal Trade Commission (FTC) responsibility for regulating labeling.¹¹ The Act further requires that the Secretary of Health and Human Services and the FTC submit annual reports concerning smoking-related health and advertising issues to Congress.¹² The FCLAA preempts any labeling requirements or regulations of advertising or promotion based on smoking and health other than those contained in the FCLAA.¹³

Related is the Comprehensive Smokeless Tobacco Health Education Act of 1986 (STA) which extends most of the requirements of the FCLAA to smokeless tobacco products.¹⁴ Tobacco product labeling is also regulated along with consumer product labels in general under the Fair Packaging and Labeling Act, enforced by the FTC, which prohibits label statements on that are misleading, unfair or deceptive.¹⁵

Another important pre-TCA tobacco regulation measure is the Tobacco Master Settlement Agreement (MSA). In the early 1990s, more than 40 states filed suit against the

⁸ 15 U.S.C. §§ 1331-1341 (1994).

⁹ 15 U.S.C. § 1331.

¹⁰ 15 U.S.C. § 1335a.

¹¹ 15 U.S.C. § 1333.

¹² Joshua L. Fogel, *Tobacco and the FDA: Conflict, Controversy and Closure* (2001) in Peter Barton Hutt, ed., *FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS*.

¹³ 15 U.S.C. § 1334

¹⁴ 15 U.S.C. § 440–4408.

¹⁵ 15 U.S.C. §§ 1451-1461

major cigarette manufacturers, seeking reimbursement of public healthcare costs incurred in the treatment of tobacco-related illnesses, on the theory that the cigarettes produced by the defendants had directly brought about the extra costs.¹⁶ “Importantly, the defenses of personal responsibility that were so effective for the tobacco industry in suits by private individuals were inapplicable to the causes of action alleged by the states.”¹⁷ Facing many suits and potentially crippling awards, the tobacco industry sought a national settlement agreement. On November 23, 1998, the country's four largest cigarette manufacturers entered into the MSA with 46 states, the District of Columbia, the Commonwealth of Puerto Rico, the U.S. Virgin Islands, American Samoa, the Northern Mariana Islands, and Guam.¹⁸

Under the MSA, the manufacturers agreed to extensive limitations on advertising and marketing of cigarettes, particularly that targeted at youth.¹⁹ Individual states were tasked with enforcement in state courts. Financially, the manufacturers agreed to make payments of about \$206 billion to the settling jurisdictions over twenty-five years.²⁰ Importantly, the MSA imposed no restrictions on how states could spend these payments. The Government Accounting Office (GAO) reported annually from 2001 to 2006 on how states were using the MSA funds.²¹ The

¹⁶ Peter Barton Hutt, Richard A. Merrill & Lewis A. Grossman, *FOOD AND DRUG LAW* 80 (3d ed. 2007). The first of these suits was declared in May 1994 by Mississippi Attorney General Mike Moore. See Michael Janofsky, *Mississippi Seeks Damages from Tobacco Companies*, N.Y. Times, May 24, 1994, at A12.

¹⁷ Robin Miller, *Validity, Construction, Application, and Effect of Master Settlement Agreement (MSA) Between Tobacco Companies and Various States, and State Statutes Implementing Agreement; Use and Distribution of MSA Proceeds*, 25 A.L.R.6th 435.

¹⁸ *Id.* (Mississippi, Florida, Texas and Minnesota settled individually before the MSA was executed).

¹⁹ Among other things, the manufacturers agreed to discontinue the targeting of youth, directly or indirectly; the use of cartoons; outdoor and transit advertising; promotion of tobacco products in motion pictures, television shows, and video games; the sale of tobacco brand-name merchandise; the distribution of free cigarettes; and the distribution of merchandise in return for proof of purchase of tobacco products, without confirming that the customer is an adult. The manufacturers also agreed to limit tobacco brand sponsorships. *Id.*

²⁰ See *id.*; Multistate Settlement Agreement, §§ IX(a), (b), (c). The states were to receive up-front payments of \$12.742 billion; annual payments, beginning April 15, 2000, of \$183.177 billion through 2025; \$861 million each year between 2008 and 2017 to the Strategic Contribution Fund; \$250 million over 10 years to the National Foundation; at least \$1.45 billion from 2000 to 2003 to the Public Education Fund; a \$50 million, one-time payment to the State Enforcement Fund; and \$1.5 billion over 10 years to the National Association of Attorneys General.

²¹ See Government Accounting Office, *States' Use of Master Settlement Agreement Payments*, GAO-01-851 (June 2001), at <http://www.gao.gov/new.items/d01851.pdf>.

GAO found that states had allocated their payments to a wide variety of activities, with some reporting that they viewed the tobacco settlement payments as an opportunity to fund those needs that they were not able to fund in the past, because of the high cost of healthcare.²² On the whole, states allocated the largest portion of their payments toward healthcare and the second largest to budget shortfalls, with only a small amount going to tobacco control, despite a CDC recommendation that at least eight percent of the funds be spent on tobacco prevention.²³ As discussed below, experts are divided on the effectiveness of the MSA.

While the regulatory scheme described above may sound extensive, no federal or state agency in this patchwork of oversight had authority to regulate tobacco products or their contents of for health and safety purposes; nor to require any tobacco manufacturer to make any change in its product.²⁴ This scheme also provided no role for the FDA. FDA did regulate tobacco products in the event that a manufacturer or vendor made an express therapeutic claim for its product, but otherwise considered tobacco products to be outside its jurisdiction.²⁵

In 1996, however, FDA asserted jurisdiction to regulate tobacco products for the first time. FDA concluded that nicotine is a “drug” within the meaning of the FDCA, in that it is

²² *Need for FDA Regulation of Tobacco: Hearing before the S. Comm. on Health, Education, Labor and Pensions on S.625*, S. Hrg. 110–100 (2007) (hereinafter “2007 Senate Hearing”) (Statement of Lisa Shames, Acting Director, Natural Resources and Environment Team, GAO).

²³ *Id.* (reporting that States allocated the largest portion of their total payments, 30 percent, toward healthcare activities, such as Medicaid, health insurance, hospitals, medical technology and research. States allocated the second largest portion of their payments, about 23 percent, to help balance their budgets or reduce their deficits. Included among the next largest categories are allocations for infrastructure projects, education, debt service on securitized proceeds. States allocated about or 3.5 percent of their total payments to tobacco control activities, such as those that address prevention, education, enforcement and cessation.)

²⁴ 2007 Senate Hearing at 190 (Testimony of Matthew L. Myers) (“The FCC’s role is limited to monitoring compliance with the decades old ban on television and radio prohibitions on tobacco advertising. The DOJ’s role is limited to enforcing potential violations of the congressionally mandated labeling requirements on cigarettes. The FTC’s role is equally limited. It enforces the specific congressionally mandated labeling requirements for smokeless tobacco products, is supposed to collect data on total tobacco industry marketing expenditures and issue a report containing that information. In addition, section 5 of the FTCA gives the FTC the law enforcement responsibility over false and deceptive marketing, as that term has been traditionally defined that includes but is not limited to tobacco.”).

²⁵ *See United States v. 46 Cartons...Fairfax Cigarettes*, 113 F.Supp. 336 (D.N.J. 1953); *United States v. 354 Bulk Cartons Trim Reducing-Aid Cigarettes*, 178 F. Supp. 847 (D.N.J. 1959). *See also Action on Smoking and Health v. Harris*, 655 F.2d 236, 239 (D.C. Cir 1980) (upholding the FDA’s refusal to regulate cigarettes).

intended to affect the structure or function of the body, and that cigarettes and smokeless tobacco are medical devices that deliver nicotine to the body.²⁶ Pursuant to this authority, FDA promulgated a rule intended to reduce tobacco consumption among children and adolescents. “The agency believed that, because most tobacco consumers begin their use before reaching the age of 18, curbing tobacco use by minors could substantially reduce the prevalence of addiction in future generations and thus the incidence of tobacco-related death and disease.”²⁷ Among other things, the rule, entitled “Regulations Restricting the Sale and Distribution of Cigarettes and Smokeless Tobacco to Protect Children and Adolescents,” prohibited the sale of cigarettes and smokeless tobacco to individuals under the age of 18; required retailers to verify a purchaser’s age by photo identification; prohibited all free samples and prohibited the sale of such products through vending machines and self-service displays except in adult-only facilities; limited advertising in publications with significant youth readership to a black-and-white, text only format; prohibited the sale or distribution of brand-identified promotional items such as hats and t-shirts; prohibited brand-name sponsorship of sporting and other events and teams, but permitted such sponsorship in a corporate name; prohibited outdoor advertising within 1,000 feet of a school or playground, and required manufacturers to provide intended use information on all cigarette and smokeless tobacco product labels and in cigarette advertising.²⁸

Tobacco manufacturers opposed FDA regulation of their products and quickly filed suit in federal district court in North Carolina, challenging the legality of the FDA’s jurisdiction.²⁹

The Supreme Court agreed with the industry. While acknowledging that tobacco use posed

²⁶ *Nicotine in Cigarettes and Smokeless Tobacco Is a Drug and These Products Are Nicotine Delivery Devices Under the Federal Food, Drug, and Cosmetic Act: Jurisdictional Determination*, 61 Fed. Reg. 44396, 44619 (Aug. 28, 1996).

²⁷ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 125 (2000).

²⁸ 61 Fed. Reg. 44396 (August 28, 1996).

²⁹ Angela R. Brooks, *A Retrospective Review of FDA v. Brown & Williamson Tobacco Corporation and the Issue of Congressional Intent* (2004) in Peter Barton Hutt, ed., *FOOD AND DRUG LAW: AN ELECTRONIC BOOK OF STUDENT PAPERS*.

“perhaps the single most significant threat to public health in the United States,” the Court held that Congress had not given FDA authority under the FDCA over tobacco products.³⁰

The Court found that part of the FDA's “mission” is to protect the public health by ensuring that drugs and devices are safe and effective and that unsafe drugs and devices be removed from the market, at least where the “potential for inflicting death or physical injury is not offset by the possibility of therapeutic benefit.”³¹ Given that the FDA had already made findings that cigarettes were inherently dangerous and deadly, if tobacco products were “devices” under the FDCA, the FDA would be required to remove them from the market.³² The Court further emphasized the fact that FDA had repeatedly and expressly disavowed any authority over tobacco products since its inception.³³ Moreover, FDA had consistently taken the position that if it did have such jurisdiction, cigarettes would have to be removed from the market because it would be impossible to prove they were safe for their intended use.³⁴ Congress, said the Court, had ratified that long-held position through decades of tobacco-specific legislation that excluded the FDA. Additionally, FDA’s regulation ran afoul of the FCLAA’s strict preemption provision.³⁵

Thus the Supreme Court ruled that if FDA were to regulate tobacco, Congress would have to expressly confer the authority upon the agency. In passing the Tobacco Control Act, Congress, nine years later, accepted the invitation.

III. The Family Smoking Prevention and Tobacco Control Act

³⁰ *Brown & Williamson*, 529 U.S. at 123.

³¹ *Id.* at 134.

³² *Id.* at 135.

³³ *Id.* at 125. *See also Action on Smoking and Health*, 655 F.2d at 239.

³⁴ *Brown & Williamson*, 529 U.S. at 137 (citing statement before Congress of FDA Commissioner Charles Edwards and statement before Congress of Department of Health, Education, and Welfare (HEW) Secretary Anthony Celebrezze).

³⁵ *Id.* at 149.

After *Brown & Williamson*, the movement to give FDA statutory authority to regulate cigarettes and smokeless tobacco products began.³⁶ A bipartisan, bicameral group of lawmakers first introduced the Family Smoking Prevention and Tobacco Control Act³⁷ in the 108th Congress. The Senate passed the bill in July 2004, but it died in the House of Representatives.³⁸ The Act was reintroduced in the 109th Congress³⁹ and again in the 110th Congress⁴⁰; during which it was approved by the House Committee on Energy and Commerce and the Senate Committee on Health, Education, Labor, and Pension (HELP). The House passed the bill in July 2008 by a wide margin, but no further action was taken in the Senate.⁴¹

Support for comprehensive FDA tobacco legislation was widespread. A crucial endorsement came from the Institute of Medicine (IOM), which singled out FDA regulation as a key step in solving America's tobacco problem.⁴² The CDC also supported the measure. Less expectedly, Philip Morris issued a white paper in 2001 in support of legislation giving FDA authority to regulate cigarettes and continued to support enactment of the TCA.⁴³

³⁶ Even before the Supreme Court's decision, but while the suit was pending in the Court of Appeals, legislators in the 105th Congress (1997-1998) tried to confer FDA authority over tobacco products as part of an unsuccessful pre-MSA attempt to legislate a proposed national tobacco settlement. Under this bill, "FDA would have to demonstrate that any proposed tobacco regulation was appropriate for the protection of public health. Such a determination would involve a consideration of the risks and benefits to the population as a whole, including both users and nonusers of tobacco products." C. Stephen Redhead and Vanessa K. Burrows, *FDA Tobacco Regulation: The Family Smoking Prevention and Tobacco Control Act of 2009*, Congressional Research Service, 3, (2009) (hereinafter "CRS Report").

³⁷ H.R. 4433, S. 2461

³⁸ Hutt, Merrill & Grossman, *supra* note 16, at 86.

³⁹ H.R. 1376, S. 666

⁴⁰ H.R. 1108, S. 625

⁴¹ CRS Report at 3.

⁴² *Id.* at 4; See also Richard J. Bonnie, Kathleen Stratton, and Robert B. Wallace, Institute Of Medicine, *Ending the Tobacco Problem: A Blueprint for the Nation* (National Academies Press 2007) at http://books.nap.edu/openbook.php?record_id=11795&page=R1.

⁴³ Phillip Morris U.S.A., *FDA and Tobacco: Why Philip Morris U.S.A. Supports Passage of Legislation in the 107th Congress Granting FDA Authority over Tobacco Products*, available at <http://legacy.library.ucsf.edu/tid/jmo20c00> (2001). For analysis of why Philip Morris has taken this position, see Patricia A. McDaniel and Ruth E. Malone, *Understanding Philip Morris' Pursuit of US Government Regulation of Tobacco*, 14 Tobacco Control 193 (2005) (available at <http://hwmaint.tobaccocontrol.bmj.com/cgi/content/abstract/14/3/193>).

The Tobacco Control Act adds a new chapter to the FDCA (Chapter IX), which authorizes the Secretary of Health and Human Services (“Secretary”) to restrict: (1) the sale or distribution of tobacco products if appropriate for the protection of the public health; and (2) the advertising and promotion of tobacco products consistent with, and to the full extent permitted by, the First Amendment.⁴⁴ The Act itself is long and complex; the following discussion attempts to highlight the major aspects of the Act and how it changes prior law.

A. Final Rule

The TCA requires FDA to reissue its 1996 tobacco rule – described above – that the Supreme Court struck down in 2000, except for the labeling requirements and any changes the Secretary finds necessary in light of governing First Amendment case law.⁴⁵

B. Public Health Standard

Central to the TCA is the new standard that it sets out for FDA action. Recognizing that tobacco products are not “safe” or “safe and effective,” the standards by which FDA measures food, drugs, and medical devices, Congress selected a different standard to guide the FDA in tobacco regulation: “appropriate for the protection of the public health.” In considering a particular regulatory measure, FDA must take into account “(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products.”⁴⁶ “The public health standard is intended to be a flexible standard that focuses

⁴⁴ 21 U.S.C. § 387f(d).

⁴⁵ 21 U.S.C. § 387a-1. The TCA refers specifically to *Lorillard Tobacco Co. v. Reilly*, 533 U.S. 525 (2001), in which the Supreme Court struck down several provisions of Massachusetts’ tobacco advertising regulations as in violation of the First Amendment.

⁴⁶ 21 U.S.C. § 387f(d).

on the overall goal of reducing the number of individuals who die or are harmed by tobacco products.”⁴⁷

C. Information

A major goal of the Act is to increase the amount of information available to the government and consumers about the contents of tobacco products. To that end, the Act requires all tobacco product manufacturers to register with the FDA and provide the agency with a detailed product list, and mandates biennial inspection of all registered establishments.⁴⁸ Tobacco product manufacturers must submit to the Secretary a listing of all ingredients in their products by brand and quantity; a description of the content, delivery, and form of nicotine in each tobacco product; a listing of smoke constituents identified by the Secretary as harmful or potentially harmful to health in each tobacco product; and all documents developed after enactment that relate to the health, toxicological, behavioral, or physiologic effects of tobacco products.⁴⁹ Manufacturers must notify the Secretary prior to adding, eliminating, increasing or decreasing the level of a new additive.

The Secretary must in turn annually publish, in an easily available and understood format, a list of harmful and potentially harmful constituents in each product brand. The Secretary must also conduct consumer research to ensure that the list is not misleading to lay persons.⁵⁰

D. Product Standards

⁴⁷ House Committee on Energy and Commerce Report, 111 H.R. Rep. No. 58 (March 26, 2009).

⁴⁸ 21 U.S.C. § 387e.

⁴⁹ 21 U.S.C. § 387d. While ingredient reporting was previously required under the FCLAA, those requirements “have proven wholly inadequate for this purpose. They do not provide the government with information to identify what chemicals and other ingredients are in each brand of cigarettes, the quantity of the different chemicals, in each cigarette or the type of information that is needed to understand or evaluate or warn the public about what is in each brand of cigarette.” 2007 Senate Hearing at 13 (prepared statement of Matthew L. Myers, President And CEO of The Campaign for Tobacco-Free Kids).

⁵⁰ 21 U.S.C. § 387d.

A significant innovation of the TCA is that it provides FDA the authority to require changes to the design and characteristics of tobacco products in order to protect public health through the issuance of product standards. Such changes could include reduction in nicotine yields; the reduction or elimination of ingredients, additives, constituents, including smoke constituents; product testing; and required labeling.⁵¹ The Secretary is prohibited, however, from banning all cigarettes or requiring the reduction of nicotine yields of a tobacco product to zero.

The Act also requires FDA to establish good manufacturing practices and critical control point methodology for tobacco product manufacturers.⁵²

E. Claims of Modified Risk

In another measure that has received much attention, the TCA requires FDA approval before a manufacturer can market a “modified risk tobacco product,” defined as a product that is sold for use to reduce harm or the risk of tobacco-related diseases.⁵³ This is broader than it might sound at first; it includes, importantly, any product marketed with descriptors such as “light,” “mild,” or “low.” It also includes any product for which labeling or advertising represents, explicitly or implicitly, that the product presents a lower risk of tobacco-related disease or is less harmful than other tobacco products, contains a reduced level of or presents a reduced exposure to a substance, or is free of a substance; or for which the manufacturer has taken action reasonably expected to result in consumers believing such things.⁵⁴

Anyone who wishes to market a modified risk tobacco product must submit an application to the Secretary. Approval will be granted only if the applicant demonstrates that the

⁵¹ 21 U.S.C. § 387g (a).

⁵² 21 U.S.C. § 387f (e).

⁵³ 21 U.S.C. § 387k.

⁵⁴ *Id.*

product, as it is actually used by consumers, will (1) significantly reduce harm and the risk of tobacco-related disease to individual tobacco users; and (2) benefit the health of the population as a whole including users and nonusers of tobacco.⁵⁵

However, this provision also sets out a less onerous approval procedure for a subset of modified risk products that have come to be known as “reduced-exposure tobacco products.”⁵⁶ A product that cannot meet the modified risk requirements may be approved for five years if any representations, on labeling or otherwise, are limited to a representation that the tobacco product or its smoke does not contain, or contains a reduced level of, or presents a reduced exposure to, a substance, if: (1) scientific evidence is not available and, using the best available scientific methods, cannot be made available without conducting long-term epidemiological studies for an application to meet the standards set forth for modified risk products; (2) the scientific evidence that is available demonstrates that a measurable and substantial reduction in morbidity among individual tobacco users is reasonably likely in subsequent studies; (3) the overall reduction in exposure to the claimed substance is substantial, such substance is harmful, and the product as actually used exposes consumers to the reduced level of the substance; (4) testing of actual consumer perception shows that, as the applicant proposes to label and market the product, consumers will not be misled into believing that the product is less harmful or presents less of a risk of disease than another marketed tobacco product; (5) approval is expected to benefit the health of the population as a whole, taking into account both users and nonusers of tobacco products.⁵⁷ Approval of a reduced exposure product is further conditioned on the applicant’s

⁵⁵ *Id.*

⁵⁶ *See, e.g.*, CRS Report at 9 (contrasting “reduced-risk” claims with “reduced-exposure” claims and concluding that it is “difficult to imagine a company gaining FDA approval to market a modified risk tobacco product based on a reduced-risk claim, at least in the near term” because meeting the standard would require long-term epidemiological studies; but that gaining approval for a new product on the basis of a reduced-exposure claim would be more feasible.).

⁵⁷ 21 U.S.C. § 387k.

agreement to conduct postmarket surveillance to determine the impact of the product on consumer perception, behavior, and health.⁵⁸

Factors that FDA must consider in approving either kind of product include the increased or decreased likelihood that existing users of tobacco products who would otherwise stop using such products will switch to the tobacco product; the increased or decreased likelihood that persons who do not use tobacco products will start using the tobacco product; and the risks and benefits to persons from the use of the tobacco as compared to the use of approved products for smoking cessation.⁵⁹

To ensure that consumers do not perceive modified risk tobacco products as “FDA Approved,” the Act further prohibits manufacturers from making any representation to consumers that conveys or would mislead consumers into believing that the product is approved by FDA; that FDA deems the product to be safe for use by consumers; that the product is endorsed by FDA for use by consumers; or that the product is safe or less harmful by virtue of its regulation or inspection by FDA or its compliance with regulatory requirements set by FDA.⁶⁰

These provisions bring tobacco in line with other FDA-regulated products, which are prohibited from making health claims without adequate scientific substantiation.⁶¹ FDA, however, has always asserted jurisdiction over cigarettes insofar as they make therapeutic claims; treating labels such as “light” and “mild” as health claims is the change, based on mounting evidence that consumers perceive these labels as indicative of a less-risky product.⁶²

⁵⁸ *Id.* See also CRS Report at 9 (noting that “approving products under the reduced exposure criteria makes postmarket surveillance all the more important as a means of monitoring the product’s actual impact on public health.”).

⁵⁹ 21 U.S.C. § 387k.

⁶⁰ Pub. L. No. 111-31, Div A, Title I, § 103 (amending 21 USC §331).

⁶¹ See 21 U.S.C. § 343 (r); 21 U.S.C. § 352 (a).

⁶² See 2007 Senate Hearing at 213 (statement of Gregory Connolly, Professor, Harvard School of Public Health and Former Director of the Massachusetts Department of Public Health’s Tobacco Control Program) (describing a study he conducted, in which tobacco product consumers were found to perceive light cigarettes and Potentially Reduced

It is worth noting that products intended to be used for the treatment of tobacco dependence are regulated as drugs or devices, and if so approved, are excluded from this section of the TCA.

F. Premarket Review of New Tobacco Products

Much as the FDCA already does for medical devices, the TCA requires the manufacturer of a new tobacco product to submit a premarket application (PMA) for FDA approval before entering the market, unless the new product is determined to be substantially equivalent to a tobacco product already on the market or it represents a minor modification of an existing product.⁶³ The Act defines “substantially equivalent” as having the same characteristics as a marketed product or having different characteristics but not raising different questions of public health.⁶⁴ FDA must approve or deny an application within 180 days of receiving it, based on the “appropriate for the protection of the public health” standard.

G. Flavored Cigarettes

The TCA prohibits cigarettes from containing any artificial or natural flavor (other than tobacco or menthol) or any herb or spice (including strawberry, grape, orange, clove, cinnamon, and vanilla) that is a characterizing flavor of the tobacco product or tobacco smoke. The legislative history indicates that this ban is intended to eliminate products that overwhelmingly target youth, as flavored cigarettes tend to be used by individuals who are experimenting with tobacco use, rather than by addicted adult smokers.⁶⁵

H. Warning Labels

Exposure Products (PREPs) as having lower health risks and carcinogens, despite the fact that no advertisements explicitly said that the products were healthy or safe; and that most smokers also believed that claims made in cigarette advertisements must be approved by a government agency.) .

⁶³ 21 U.S.C. § 387j. Under this provision, products that are marketed within 21 months of enactment may be introduced into the market while their PMAs are pending.

⁶⁴ *Id.* The meaning of “not raising different questions of public health” will be discussed below.

⁶⁵ See 111 H.R. Rep. No 58.

The new law amends the FCLAA to replace the existing required health warning labels with nine more explicit health warnings, which must appear in bold type and occupy at least fifty percent of the front and back panels of cigarette packages.⁶⁶ FDA can adjust the format and size requirements and require tar, nicotine yield, or other constituent disclosures through rulemaking.⁶⁷ The FDA can also require new or different label statements, in a new exception to the FCLAA's preemption provision.

The TCA also directs FDA to issue regulations that require color graphic labels depicting the negative health consequences of smoking.⁶⁸ Graphic warning labels, which are currently used in Europe, Canada, and some Asian countries, are meant to add "a bit of a shock"⁶⁹ to potential smokers and are recommended by the World Health Organization.⁷⁰ FDA is directed to coordinate with FTC in implementing and overseeing the new labeling and advertising requirements.⁷¹

I. Preemption

The TCA cuts back, but does not fully eliminate, the FCLAA's broad preemption of any state regulation of cigarette marketing, in place since 1969. The TCA amends the FCLAA to allow states or localities to impose specific bans or restrictions on the time, place, and manner, but not the content, of the advertising or promotion of any cigarettes.⁷² The states already have this authority for smokeless tobacco products.

⁶⁶ Pub. L. No. 111-31, Div A, Title II, §§ 201 (amending 15 U.S.C. § 1333). The Comprehensive Smokeless Tobacco Health Education Act of 1986 is amended to apply similar restrictions on labeling and advertising to smokeless tobacco products. *Id.* § 204.

⁶⁷ *Id.* at §§ 201, 206.

⁶⁸ *Id.* at § 201.

⁶⁹ 155 Cong. Record S. 6497, 6499 (Statement of Senator Enzi)

⁷⁰ See World Health Organization, *The Impact of Pictures on the Effectiveness of Tobacco Warnings*, at <http://www.who.int/bulletin/volumes/87/8/09-069575/en/>

⁷¹ 21 U.S.C. § 387n.

⁷² P.L. 111-31, Div A, Title II, § 203.

The TCA further preserves state authority to enact laws in addition to or more stringent than those established under the TCA relating to the sale, possession, exposure to, access to, advertising and promotion of, or use of tobacco products by individuals of any age, information reporting to the State, or measures relating to fire safety standards for tobacco products.⁷³ It preempts, however, any state law which is different from or in addition to any requirement under the TCA relating to tobacco product standards, premarket review, adulteration, misbranding, labeling, registration, good manufacturing standards, or modified risk tobacco products.⁷⁴

J. Product Testing

The TCA requires FDA to develop new regulations for the testing, reporting, and public disclosure of tobacco product ingredients and smoke constituents, including tar and nicotine levels.⁷⁵ This testing would replace the “FTC method,” the current system that the FTC uses to test smoke constituents. This system has been faulted with miscalculating “light” and “low tar” cigarettes as presenting lower yields of tar and nicotine, which as actually used by smokers they do not, and thus allowing them to be falsely marketed for decades as less risky products.⁷⁶

K. User Fees

To cover the costs of FDA regulation of tobacco, FDA will assess a quarterly user fee on manufacturers and importers of tobacco products based on the class of tobacco product and the company market share.⁷⁷ The TCA allows other FDA funds to be used for tobacco regulation

⁷³ 21 U.S.C. § 387g. Thus states are free to continue pursuing policies such as smoke-free workplace laws, tobacco taxes, age requirements, identification checks, retailer licensing and fines, and other restrictions on the sale and distribution of tobacco products that have been instrumental in reducing tobacco use in the past several years. 2007 Senate Hearing at 181 (Testimony of Matthew L. Myers). Of course, state regulation in this area will still be subject to the First Amendment.

⁷⁴ 21 U.S.C. § 387g.

⁷⁵ 21 U.S.C. § 387o.

⁷⁶ See, e.g., National Cancer Institute, *Monograph 13: Risks Associated with Smoking Cigarettes with Low Machine-Measured Yields of Tar and Nicotine* (2001), at <http://cancercontrol.cancer.gov/tcrb/monographs/13>.

⁷⁷ 21 U.S.C. § 387s.

activities before October 1, 2009, but requires that any FDA funds used on such activities be reimbursed with the user fees.

L. Internet Sales

Under the TCA, FDA must promulgate regulations to prevent the sale and distribution of tobacco products to minors through means other than a direct, face-to-face exchange between a retailer and a consumer (e.g., Internet or mail-order sales).⁷⁸ This is a key component in fighting tobacco sales to children, as studies show that it is very easy for minors to purchase cigarettes over the Internet.⁷⁹

M. Limitations

It is important to note some of the limits that the TCA places on FDA authority. First, as already mentioned, the FDA cannot ban cigarettes or require that nicotine levels be reduced to zero. Nor can the FDA limit the sale or distribution of a tobacco product to by prescription only; prohibit the sale of a tobacco product in face-to-face transactions by a specific category of retail outlets; or establish a minimum age of sale of tobacco products to any person older than 18 years of age. The main concern is that suddenly removing cigarettes or nicotine from the market or severely limiting access to them would cause a public health crisis, leaving 40 million people without a way to satisfy their drug dependency; and potentially leading to an illegal black market.⁸⁰ These are considerations the FDA must take into account in exercising its authority under the TCA to lower nicotine levels.⁸¹

The legislation does not ban menthol; however, it authorizes FDA to ban or modify the use of menthol in cigarettes in the future based on scientific evidence. In part because of the

⁷⁸ 21 U.S.C. § 387f.

⁷⁹ See, e.g., Kurt M. Ribisl, Rebecca S. Williams, & Annice E. Kim, *Internet Sales of Cigarettes to Minors*, 290 JAMA 1356 (2003).

⁸⁰ See 111 H.R. Rep. No 58; 2007 Senate Hearing at 5 (Statement of Senator Kennedy).

⁸¹ See 21 U.S.C. § 387g (b).

disproportionate prevalence of menthol cigarette use among African Americans, Congress wanted FDA to gather more scientific evidence before removing these products from the market.⁸² Nor does the Act ban flavorings in tobacco products other than cigarettes.

IV. Criticism

Much controversy surrounds the Tobacco Control Act. Among those who share a goal of solving America's tobacco problem, there is disagreement over whether government regulation of tobacco products is a good idea at all and, if so, whether the measures of the TCA are an effective way to accomplish it. Several major points of contention have emerged.

A. FDA is Not the Appropriate Agency to Regulate Tobacco

There has been much division over whether FDA is the appropriate candidate to undertake tobacco regulation. Many believe that regulating an inherently unsafe product is contrary to FDA's core mission of ensuring safety and effectiveness in products it regulates.⁸³ There is concern that since the power to remove health threats from the marketplace is one of FDA's key tools for protecting the public health, forcing FDA to regulate a product it has already determined to be unsafe for its intended use while tying its hands from removing that product from the market will undermine FDA's perceived and actual effectiveness.

Another argument against placing this power with FDA is that the agency already has more responsibility than it can manage with food, drugs, devices and cosmetics, and lacks adequate funding for even those regulatory activities. Critics note the current lag in approval for new drugs and food additives,⁸⁴ and question how FDA could possibly handle a whole new set of PMAs for new tobacco products and meet the 180 day deadline for action. Creation of product

⁸² 111 H.R. Rep. No 58.

⁸³ See, e.g., 2007 Senate Hearing (Statements of Senator Enzi). Ultimately Senator Enzi supported FDA regulation of tobacco products.

⁸⁴ See, e.g., Peter Barton Hutt, *The Regulation of Drug Products by the United States Food and Drug Administration*, in Hutt, Merrill and Grossman, *supra* note 16, at 676.

standards, too, would be a significant burden. There are more than 4,000 chemical compounds in tobacco smoke, including about 60 known carcinogens. “Researchers still know relatively little about the precise mechanisms by which individual compounds and groups of related compounds contribute to the overall health risks of smoking. It may take years to collect the data necessary to demonstrate that the reduction or elimination of a particular tobacco product constituent will lead to an improvement in public health.”⁸⁵ Even then, “[t]he only way to know whether any reductions in specific constituents of tobacco smoke would result in a safer product would be to conduct long-term studies, using smokers as guinea pigs.”⁸⁶

Proponents of FDA regulation respond that FDA is uniquely suited to regulate tobacco products; that FDA’s mission is not to pull unsafe products off the shelves, but to protect the public health. Mitigating the impact of tobacco products is a crucial part of that effort.

Moreover, proponents point out that if tobacco products are to be regulated for health purposes, FDA’s expertise makes it the natural candidate. Notwithstanding the Supreme Court’s holding in *Brown & Williamson*, nicotine is a drug and cigarettes and tobacco are mechanisms for delivering nicotine to the body; “FDA has more experience and sophistication in the regulation of drugs and drug delivery systems than any agency in the world.”⁸⁷ Unlike the FTC, the other likely candidate for tobacco regulation, FDA personnel possess scientific, medical and public health experience and can conduct scientific research, all of which are necessary to keep

⁸⁵ CRS Report at 11.

⁸⁶ 2007 Senate Hearing at 59 (Prepared Statement of Alan Blum). But note that the WHO recommends government-mandated lowering of the levels of toxic constituents in cigarette smoke. See Report of the fourth meeting of the WHO Study Group on Tobacco Product Regulation, *Recommendation On Mandated Lowering Of Toxicants in Cigarette Smoke: Tobacco-Specific Nitrosamines And Selected Other Constituents* (2007) , at http://apps.who.int/gb/ebwha/pdf_files/EB124/B124_32-en.pdf.

⁸⁷ *Id.* at 41 (Prepared Statement of Jack Henningfield, Ph.D., President, Research and Health Policy, Pinney and Associates, and Professor of Behavioral Biology at Johns Hopkins University School of Medicine).

up with a sophisticated and changing chemical product.⁸⁸ FDA already regulates tobacco cessation products, such as nicotine patches and gums, experience which should certainly be relevant to regulation of tobacco products. FDA additionally has unique experience in developing and enforcing product performance standards and in determining the appropriate kind and amount of information to deliver to consumers about products that will affect the body. There is also value in consolidating regulation, allowing one agency to study and regulate the levels of the chemicals in tobacco products, as well as to determine what marketing claims are permissible, particularly with respect to which products are safer than others.⁸⁹

With respect to FDA's workload, supporters point out that under the TCA, industry research would be made available to the FDA and the industry would be required to conduct the bulk of testing of new and existing products. They also point out that Canada requires extensive testing of tobacco and smoke constituents and CDC already receives ingredient lists for manufacturers, as does Texas by brand. "If these jurisdictions already receive this information, it should not be burdensome for FDA."⁹⁰

As one alternative to FDA regulation, some propose improving and putting more resources into the MSA. Smoking levels have dropped since implementation of the MSA,

⁸⁸ See Hearing before the Committee on Energy and Commerce Subcommittee on Commerce, Trade, and Consumer Protection, U.S. House of Representatives (Testimony of Timothy Muris, FTC Chairman) (June 3, 2003) (stating that FTC is "an agency of lawyers and economists" and does not have the necessary scientific, medical and public health expertise to evaluate scientific claims and data regarding tobacco products).

⁸⁹ *Id.* at 78 (Testimony of Gregory Connolly) (arguing that both advertising and chemical manipulation are used in tandem to target children, and thus must be regulated together). Compare this to the area of prescription drugs, in which FDA has jurisdiction over advertising and labeling even though FTC regulates these aspects of over-the-counter drugs.

⁹⁰ 2007 Senate Hearing at 219 (Testimony of Gregory Connolly). See also *Id.* at 87 (Testimony of Jack Henningfield) ("what FDA is already good at, for better and for worse, is sitting back and letting the companies spend the money and say, 'Prove it.'"); *Id.* at 207 (Testimony of Jack Henningfield) (noting that FDA can require sponsors to conduct studies and present data on consumer reactions and actual patterns of use of their products; and can require companies to collect and report their own data after their products are marketed).

though they have leveled off in recent years.⁹¹ Dr. Elmer Huerta, President of the American Cancer Society, responds that the MSA has done little to stop youth-oriented tobacco advertising, which was its main purpose.⁹² The MSA put no restrictions on print media advertising or in-store tobacco advertising, which actually increased after the MSA; permitted outdoor signs up to 14 square feet in size, even if placed next to schools or playgrounds; and lacks effective mechanisms for detecting and punishing violations.⁹³ Nor does the MSA address Internet tobacco advertising or sales. Dr. Huerta alleges that tobacco companies have actually increased marketing to youth since the MSA, only in different ways.⁹⁴

B. Harm Reduction

Another controversial aspect of the TCA is that it does not embrace “harm reduction,” a strategy which entails encouraging smokers who will not or cannot quit to switch to smokeless tobacco products, which have been shown to present lower risks of cancer and other tobacco-related illness and death than cigarettes. Many believe harm reduction to be a crucial and pragmatic step in reducing smoking levels and tobacco-related illness and death; it has the support of the American Association of Public Health Physicians⁹⁵ and has been cautiously supported by the Institute of Medicine as well.⁹⁶ The goal of the strategy is to place tobacco

⁹¹ See, e.g., Frank A. Sloan and Justin G. Trogon, *The Impact of the Master Settlement Agreement on Cigarette Consumption*, 23 J. Pol’y Analysis and Mgmt 843 (2004); American Association of Family Physicians, *Recent Decline in U.S. Smoking Prevalence Stalls* (2009), at <http://www.aafp.org/online/en/home/publications/news/news-now/health-of-the-public/20091119smoke-stats.html>

, http://www.cdc.gov/tobacco/data_statistics/tables/trends/cig_smoking/index.htm

⁹² 2007 Senate Hearing at 19-20 (Statement of Elmer Huerta).

⁹³ *Id.*

⁹⁴ Dr. Huerta highlighted two recent tobacco marketing efforts, Brown & Williamson’s “Kool Mixx” campaign and RJ Reynolds’ candy-flavored cigarettes, that appear to be directly targeted to youth, using hip-hop images and scratch-and-sniff advertisements, respectively.

⁹⁵ See Joel L. Nitzkin and Brad Rodu, *The Case for Harm Reduction for Control of Tobacco-Related Illness and Death*, AAPHP Resolution and White Paper (2008), at <http://www.aaphp.org/special/joelstobac/20081026HarmReductionResolutionAsPassedl.pdf>

⁹⁶ See Kathleen Stratton, Padma Shetty, Robert Wallace, and Stuart Bondurant, Eds., Board on Health Promotion and Disease Prevention, IOM, *Clearing the Smoke: Assessing the Science Base for Tobacco Harm Reduction* (Nat’l Academy Press 2001) (“the potential for reduction in morbidity and mortality that could result from the use of less

products on a continuum of risk, and to encourage users to move down the continuum.⁹⁷

Substitutes for the TCA incorporating harm reduction strategies were offered in both the House and Senate.

However, opponents of harm reduction fear that “promoting smokeless tobacco as a safer alternative to smoking will undermine efforts both to discourage youngsters from using smokeless tobacco and to encourage adult smokers to give up tobacco products altogether.”⁹⁸ The WHO’s Scientific Advisory Committee on Tobacco Products Regulation has concluded that a harm reduction strategy using smokeless tobacco products is not appropriate; specifically, that the claimed benefits have not been demonstrated and that the risks for harm are great.⁹⁹ It was this view that ultimately carried the day in drafting the TCA. With several nicotine-replacement therapies and new smoking-cessation prescription drugs already approved as safe by the FDA, harm reduction seemed needlessly risky.¹⁰⁰ There was also concern that smokeless tobacco products are increasingly being designed to attract youth to start using tobacco, rather than to wean existing smokers to a safer product.¹⁰¹ Opponents of harm reduction point out that if a tobacco product really does reduce risk of harm, manufacturers are free to submit a modified risk tobacco product application and market it as such.

toxic products by those who do not stop using tobacco justifies inclusion of harm reduction as a component in a broad program of tobacco control.... [T]here can be a successful, scientifically-based harm reduction program that is justifiable and feasible—but only if implemented carefully and effectively...”).

⁹⁷ 155 Cong Rec. H. 4412, 4341 (2009)

⁹⁸ CRS Report at 8.

⁹⁹ See WHO Scientific Advisory Committee on Tobacco Products Regulation, *Recommendation on Smokeless Tobacco Products* (2008), at http://www.who.int/tobacco/sactob/recommendations/en/smokeless_en.pdf (finding that there is conclusive evidence that certain smokeless tobacco products increase risk of oral cancer; that smokeless tobacco products are addictive; that users of both smokeless and smoking products find tobacco cessation even more difficult to achieve than those who use only smokeless tobacco or only smoke; that youth are especially vulnerable to initiating smokeless tobacco use; and that use of smokeless tobacco products has not been shown to be an effective smoking cessation aid.). See also HHS Agency for Healthcare Research and Quality (AHRQ), Clinical Practice Guideline (revised 2000), *Alternative Treatment Goals: Harm Reduction* (finding insufficient evidence to support a recommendation regarding harm reduction interventions).

¹⁰⁰ See 155 Cong Rec. H. 4412, 4368 (2009)

¹⁰¹ See 155 Cong Rec. S. 5994, 5999 (2009) (pointing out that candy-flavored Snus should be subject to at least the same regulatory oversight as nicotine chewing gum).

C. Reduced Incentive to Produce Less Harmful Products

The TCA has also been criticized on the ground that it will reduce incentive for tobacco manufacturers to develop and market products that reduce exposure to tobacco toxic substances. Because the standard for claims of modified risk is so difficult to meet, companies will not create modified risk products in the face of such small odds that they will be able to market them. James T. O'Reilly opines that “[i]f a truly healthier cigarette were to be invented, the 2009 Act erects substantial hurdles which disincentivizes the investment needed to reach the market.”¹⁰²

Skeptics respond that the scientific evidence standard is necessary because the tobacco industry has a consistent track record of marketing its products as healthier when they were not – in particular, “light” and “low tar” cigarettes. Moreover, the reduced-exposure standards are sufficiently relaxed to provide incentive to reduce the levels of certain substances in tobacco products. The TCA also directs the Secretary to consider a fast track approval process for products that are actually intended for treatment of tobacco dependency.¹⁰³

D. The Tobacco Control Act is Too Limited to be Effective

On the other side, some condemn the TCA for not going far enough. Some worry that the more lenient approval procedure for “reduced exposure” claims will swallow the modified risk product provisions altogether. For instance, consumers may not be able to distinguish between claims of reduced exposure and reduced risk.¹⁰⁴ Indeed the impetus for the modified risk provision was consumers’ tendency to perceive terms like “mild” and “low tar” as assurances of reduced risk. The TCA does seek to combat such confusion, however. The reduced exposure provision is designed to ensure that approved products genuinely provide

¹⁰² James T. O'Reilly, *FDA Regulation of Tobacco: Blessing or Curse for FDA Professionals?* 64 FOOD DRUG L.J. 459, 466.

¹⁰³ 21 U.S.C. § 387r.

¹⁰⁴ See 2007 Senate Hearing at 59 (Prepared Statement of Alan Blum M.D., Director, University of Alabama Center for the Study of Tobacco and Society).

reduced levels of harmful substances as actually used. The TCA also requires postmarket surveillance of the impact of modified risk products on consumers and authorizes FDA to withdraw approval of a product if it appears the public is being misled. The effectiveness of the modified risk product provisions may thus turn on how well that surveillance system works in practice.

Many critics are upset that menthol was not banned along with other cigarette flavors. Menthol cigarettes frequently contain among the highest levels of nicotine among cigarettes. There is also evidence that it is harder to quit smoking menthols.¹⁰⁵ Although the TCA does require FDA to consider banning menthol in the future, some see its exemption as a concession to Phillip Morris, which produces Newport.

Another criticism is that that TCA actually makes it too difficult for FDA to act in practice. O'Reilly maintains that the TCA imposes procedural barriers on FDA action that do not exist for other products that FDA regulates, which may ultimately impede any rulemaking.¹⁰⁶

V. Analysis

The Tobacco Control Act has potential to reduce smoking levels and radically change the U.S. tobacco market. Indeed, flavored cigarettes and those labeled as “light” or “mild” have already disappeared from the shelves. However, certain aspects of the Act threaten its efficacy.

The meaning of the TCA will ultimately turn on how the standard “appropriate for the protection of the public health, taking into account the risks and benefits to the population as a whole, including users and nonusers of tobacco products” is interpreted by FDA – and, eventually, the courts, if and when the tobacco industry challenges FDA action under the Act.

¹⁰⁵ CRS Report at 12. *See also* Letter from seven former HHS Secretaries to members of the House and Senate urging them to ban the use of menthol in cigarettes (June 2008) (available at http://www.nytimes.com/2008/06/05/business/05TobaccoLetter.html?_r=2&scp=5&sq=menthol&st=cse&oref=slog in).

¹⁰⁶ *See* O'Reilly, 460-65.

Congress intended the standard to be a flexible one,¹⁰⁷ but the dual requirements that the FDA must consider, in taking any action, “(A) the increased or decreased likelihood that existing users of tobacco products will stop using such products; and (B) the increased or decreased likelihood that those who do not use tobacco products will start using such products” could severely limit FDA authority. For instance, if FDA promulgated a rule requiring reduction of a smoke constituent, the TCA’s test could be interpreted as obliging FDA to come forth with scientific evidence of increased likelihood that existing users would stop using the affected product *and* increased likelihood that non-users would refrain from initiating use. That would be a very high burden.

Product testing, which will be necessary to FDA exercising its authority to promulgate product standards, will only be as good as the testing methods. If FDA’s methods do not make significant scientific improvements over the FTC method, tobacco manufacturers will be free to undermine the new legislation as they have with past tests for tar and nicotine yields.

Another problem that could arise under the Act is that the premarket approval provisions contain a potentially significant loophole: a product is deemed to be “substantially equivalent” to an already-marketed product if it “does not raise different questions of public health.”¹⁰⁸ How FDA defines “questions of public health” will be very important. If a new product can enter the market without approval on the basis that it raises the same public health questions of addiction and cancer, then the premarket approval procedure would be worthless.¹⁰⁹

In the area of modified risk products, it is not clear how FDA will go about proving that a product makes an implicit claim of reduced risk. Products such as PREPs do not contain any explicit claims in their labels or advertising that they are healthier, but people have been shown

¹⁰⁷ See 111 H.R. Rep. No 58.

¹⁰⁸ 21 U.S.C. § 387j.

¹⁰⁹ O’Reilly at 469.

to interpret the products that way. Will FDA have to conduct controlled consumer studies for each advertisement in order to prove an implicit claim has been made? Could FDA demand that the manufacturer conduct such studies?

It is also likely that at least some of the TCA's advertising and marketing restrictions, particularly some of those in the Final Rule, would not withstand a First Amendment challenge. Restrictions on commercial speech are subject to the four-part test set out in *Central Hudson Gas & Electric Corp. v. Public Serv. Comm'n.*¹¹⁰ First, the speech in question must concern a lawful activity and not be misleading; second, the government must show that there is a substantial government interest at stake; third, the regulation must directly advance the government's interest; finally, the restriction must be not more extensive than necessary to serve that interest.¹¹¹ Reducing adolescent use of tobacco products is certainly a substantial government interest, and the restrictions in the Final Rule advance that interest by reducing underage exposure to tobacco advertising. However, some would likely be found by a court to sweep more extensively than necessary.

In *Lorillard Tobacco Co. v. Reilly*,¹¹² the U.S. Supreme Court struck down provisions of a Massachusetts statute that, like the FDA Final Rule, banned outdoor ads within 1,000 feet of schools, parks and playgrounds and restricted in-store advertising of tobacco products. The Court found that these restrictions failed the requirement of *Central Hudson* that there be "a reasonable fit between the means and ends of the regulatory scheme," in that they effected a flat ban on tobacco advertising "in a substantial portion of the major metropolitan areas of Massachusetts"; this "uniformly broad sweep of the geographical limitation demonstrates a lack

¹¹⁰ 447 U.S. 557 (1980).

¹¹¹ *Id.* at 564-66.

¹¹² 533 U.S. 525 (2001).

of tailoring.”¹¹³ The Court noted, albeit in dicta, that since the Massachusetts statute was based on the FDA's rule, the FDA rule would have similar unconstitutional effects on a nationwide basis.¹¹⁴

FDA could run into further First Amendment problems with the TCA's restrictions on modified risk claims. To the extent that a tobacco manufacturer seeks to convey to consumers truthful information about its product – for example, that it contains less tar than another brand of cigarette – the government would have to come forth with evidence that such claims are misleading to the public, or that requiring evidence of substantial reduction in the substance is narrowly tailored to the interest in promoting public health, in order to justify its restriction on such claims. Moreover, on January 10, 2010, FDA published a request for comments in developing its guidance on the meaning of “similar descriptors” to the terms “light,” “mild,” and “low,” which the TCA prohibits on labels and advertising.¹¹⁵ FDA suggested some descriptors it believes might be similar, including use of colors on packages like white, silver or pastels. It is difficult to imagine a ban on use of such colors surviving First Amendment scrutiny.

One way to demonstrate some of these problems is to apply the TCA to a relatively new tobacco product called Snus. A dissolvable smokeless tobacco product that comes in individual packets and a variety of flavors and does not require the user to spit, Snus was held out during the legislative debates as a prime example of why FDA regulation was needed. However, it is not clear that the TCA would prohibit or alter Snus in any way if the product were marketed after enactment. First, it does not appear that Snus raises any different questions of public health from traditional chewing tobacco, so it would probably be marketable as a substantially equivalent

¹¹³ *Id.* at 563.

¹¹⁴ *Id.* Although the Massachusetts law included oral communications and the FDA Rule does not, the holding did not rest on that basis.

¹¹⁵ 75 Fed. Reg. 2879 (January 19, 2010).

product.¹¹⁶ It comes in candy flavors, but the ban on such flavors does not reach smokeless tobacco products. Senator Merkley pointed out with outrage that the product comes in a dispenser shaped like a cell phone that delivers the tablets in a similar fashion to a Pez dispenser.¹¹⁷ On their own, these features might not be enough evidence of marketing to youth for FDA to prohibit the product under the Final Rule or the “appropriate for the public health” standard. If FDA wants to effectively regulate products like Snus, some of these loopholes will have to be closed.

VI. Conclusion

The Family Smoking Prevention and Tobacco Control Act is clearly a step in the right direction. It forces tobacco manufacturers to account for marketing claims with scientific evidence, prohibits some of the most egregious marketing techniques that have been found to appeal to children, and allows government scrutiny of tobacco product constituents for the first time in U.S. history. The FDA’s mandates under the TCA, however, may prove difficult to implement in practice. Hopefully the Act will be given the flexible interpretation it needs to be effective.

¹¹⁶ Even if not, it would be allowed to enter the market pending review if marketed within 21 months of enactment of the TCA.

¹¹⁷ 155 Cong Rec. S. 5994, 5999 (2009).